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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
[illegible]	[illegible]	NICASSON	RAF/20713/NI

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EXAMINER	
WORTMAN, D	
ART UNIT	**PAPER NUMBER**
[illegible]	14

DATE MAILED: [illegible]

Please find below and/or attached an Office communication concerning this application or pr ceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/147,801	Niklasson
Examiner	**Group Art Unit**
Donna C. Wortman, Ph.D.	1648

☒ Responsive to communication(s) filed on *Oct 23, 1900*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-7, 9-12, and 14-16* is/are pending in the applicat

Of the above, claim(s) *1-3 and 5* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *4, 6, 7, 9-12, and 14-16* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-7, 9-12, and 14-16* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *3 1/2*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice to Comply ... SEQ

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

This application fails to comply with the sequence rules 37 C.F.R. 1.821 - 1.825 because it contains numerous sequences that do not appear on the CRF and in the sequence listing supplied on 8/21/00. In particular, the sequence listing has only four sequence ID numbers; however, more sequences are disclosed, such as the primers that appear on pages 6 and 7 and the additional sequences, including prior art sequences, that appear in Tables 2 and 3, for example. There may be others as well. In addition, all sequences that appear in the text and figures must be accompanied by the appropriate SEQ ID NO. Please see the attached Notice to Comply. Applicant is given the same time in which to comply with the sequence rules as is available to respond to this Office action.

Applicant's election of Group II, claims 4, 6, 7, 9-12 and 14-16 in Paper No. 13 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 1-3 and 5 have been withdrawn from consideration as drawn to non-elected inventions. Claims 4, 6, 7, 9-12 and 14-16 are under examination insofar as each is drawn to, or deemed to read on, the elected subject matter.

A copy of PTO 1449 is attached. Listed references that are lined out have not been considered because the statement does not comply with 37 CFR 1.98(2) which requires that copies of all cited documents be submitted; there is no indication that copies of any references were submitted or received.

Claims 4, 6, 7, 9-12 and 14-16 are objected to because of the following informalities: Generally, independent claims should be introduced by the indefinite article "A" and dependent claims should be introduced by the definite article "The." Appropriate correction is required.

Claims 6, 7, 10-12 and 14-16 are objected to because of the following informalities: Claims 6, 7, 10-12 and 14-16 either depend from non-elected claims or recite material that does not read on the elected invention, viral proteins and kits or vaccines comprising those proteins. Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 6, 7, 9-12 and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite in reciting "homologous sequences having at least 75% homology to SEQ ID NO:4" since neither "homologous sequences" nor "homology" has been defined in the specification such that one of skill in the art could reasonably determine what Applicant intends by the cited terminology. Is "homology" intended to mean the same as "identity," or does Applicant intend "homology" to encompass chemical, immunological, and/or functional homology, e.g.? If functional homology

is intended, what function is required? It is not possible to determine the metes and bounds of claim 4 as presently recited.

Claim 6 is indefinite in reciting "at least a part of a structural protein" since a part of a protein can be as little as a single amino acid.

Claim 9 is indefinite because it depends from cancelled claim 8.

Claims 11 and 12 provide for the use of a viral antigen to prepare a medicament, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 11 and 12 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 14 is indefinite because it depends from cancelled claim 13.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 6, and 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a protein that comprises the amino acid sequence of SEQ ID NO:4 does not reasonably provide enablement for a protein that comprises homologous sequences having at least 75% homology to SEQ ID NO:4 nor for antigenic fragments of the sequences, nor for "at least a part" of an antigenic protein of a picornavirus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. With respect to claim 4, the terms "homologous" and "homology" are indefinite, as discussed above. The specification does not teach how to make and use proteins that are in some sense "homologous" to SEQ ID NO:4 since no "homologous" proteins are disclosed. Even if "homologous" is taken in a more restrictive sense to mean "identical," the specification does not provide disclosure that is commensurate in scope with the claim, since it does not disclose proteins comprising amino acid sequences that are at least 75% identical to SEQ ID NO:4 and does not teach how to, or provide guidance as to, obtaining, making, and using such proteins. Further, the specification does not teach or identify which "fragments" of the protein are antigenic nor does it teach how to make and use antigenic fragments, nor, with respect to claims 6 and 7, does it identify or teach how to make and use an antigen that represents "at least a part" of a picornavirus structural protein, since it does not identify which part of the protein is antigenic, i.e., would be expected to raise antibodies that could be identified as diagnostic.

Claims 9-12 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 9-12 and 14-16 are drawn to claims involving vaccines or treatments for diseases or conditions that may be caused by the Ljungan virus. The specification does not provide factual evidence that any known diseases or pathological conditions are in fact caused by the Ljungan virus. Niklasson et al. (Virology 255:86-93, 1999, cited on PTO 892, attached), published well after the foreign priority date of the instant application, state that, although the goal of the study was to find new etiologic agents causing myocarditis in humans, "... thus far we have been unable to demonstrate a pathogenetic role of the Ljungan virus isolates as the causative agents of human disease ..." (page 90, first full paragraph in col. 1). Consequently, the specification cannot be said to enable one skilled in the art to make and use the invention with respect to vaccines or treatments for diseases or conditions caused by the Ljungan virus.

A claim drawn to a protein that comprises the amino acid sequence of SEQ ID NO:4 would be allowable. A search of the prior art does not indicate that a Ljungan virus protein that comprises the amino acid sequence of SEQ ID NO:4 was known at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Wortman whose telephone number is (703) 308-1032. The examiner can normally be reached on Monday through Thursday from 7:30 am to 5:00 pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached at (703) 308-4027. Any inquiry of a general

nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Donna Wortman, Art Unit 1648, and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1648 FAX telephone number for official papers is (703) 308-4242. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday, or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

Donna C. Wortman, Ph.D.
Primary Examiner

December 14, 2000